

PATENT COOPERATION TREATY

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From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
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PCT

WRITTEN OPINION

(PCT Rule 66)

Applicant's or agent's file reference 4239-66176		Date of Mailing (day/month/year) 22 JUN 2004 REPLY DUE within 1 months/days from the above date of mailing
International application No. PCT/US03/20367	International filing date (day/month/year) 26 June 2003 (26.06.2003)	Priority date (day/month/year) 28 June 2002 (28.06.2002)
International Patent Classification (IPC) or both national classification and IPC IPC(7): C07H 21/04; C07K 16/00; A61K 39/395; G01N 33/53 and US Cl.: 536/23.53; 435/320.1, 7.1; 530/387.1, 388.85, 391.1; 424/133.1, 156.1, 181.1		
Applicant THE GOVERNMENT OF THE UNITED STATES OF AMERICA AS REPRESENTED BY THE SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES		

<p>1. This written opinion is the <u>first</u> (first, etc.) drawn by this International Preliminary Examining Authority.</p> <p>2. This opinion contains indications relating to the following items:</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 60%;"> <p>I <input checked="" type="checkbox"/> Basis of the opinion</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2 (a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p> </div> <div style="width: 35%; text-align: right;"> <p>LOCKETED FOR: <u>7/22/04</u></p> <p>COMPUTER <input checked="" type="checkbox"/></p> <p>CHAD <input checked="" type="checkbox"/></p> <p>BOOK <input checked="" type="checkbox"/></p> <p>BOOK <input checked="" type="checkbox"/></p> <p>BOOK <input checked="" type="checkbox"/></p> <p>ANN. SVE <input type="checkbox"/></p> </div> </div> <p>3. The applicant is hereby invited to reply to this opinion.</p> <p style="margin-left: 40px;">When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension. See rule 66.2(d).</p> <p style="margin-left: 40px;">How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.</p> <p style="margin-left: 40px;">Also For an additional opportunity to submit amendments, see Rule 66.4. For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis. For an informal communication with the examiner, see Rule 66.6</p> <p style="margin-left: 40px;">If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.</p> <p>4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: <u>28 October 2004 (28.10.2004)</u></p>		<p>Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230</p>	<p>Authorized officer <i>Jalene Bell-Harris</i> Larry R. Helms Telephone No. 571/272-1600</p>
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International application No.

PCT/US03/20367

1. Basis of the opinion

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed
- ☒ the description:
pages 1-55, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____
- ☒ the claims:
pages 56-63, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of _____
- ☒ the drawings:
pages 1-9, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____
- ☒ the sequence listing part of the description:
pages 1-5, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- ☒ contained in the international application in printed form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE _____
- ☐ the claims, Nos. NONE _____
- ☐ the drawings, sheets/fig NONE _____

5. ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."

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V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims <u>2-3, 20, 23-31, 51, 53-54</u>	YES
	Claims <u>1, 4-19, 21-22, 32-50, 52</u>	NO
Inventive Step (IS)	Claims <u>2-3, 20, 23-31</u>	YES
	Claims <u>1, 4-19, 21-22, 32-54</u>	NO
Industrial Applicability (IA)	Claims <u>1-54</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 1, 4-19, 21-22, 32-50, 52 lack novelty under PCT Article 33(2) as being anticipated by WO 00/26394, 5/11/2000.

The claims are summarized as humanized CC49 antibody with non-conservative substitution in CDR3 of the light chain and CDR1 and 2 are from a human, wherein the antibody comprises an effector, label, toxin, a nucleic acid, vector, method of detecting, method of treating a tumor, and compositions comprising the antibody.

WO 00/26394 teach all of the above as indicated in the international search report (see Figure 2, page 25, lines 1-11, page 14, line 15-22, page 14-19).

Therefore, Claims 1, 4-19, 21-22, 32-50, 52 lack novelty under PCT Article 33(2) as being anticipated by WO 00/26394, 5/11/2000.

Claims 51, 53-54 lack an inventive step under PCT Article 33(3) as being obvious over WO 00/26394, 5/11/2000.

The claims are summarized as a method of treating a subject having a tumor that expresses TAG-72 by administering an antibody of claim 1 with a radioactive isotope and detecting the immune complex and removing the tumor surgically and a kit comprising the antibody.

WO 00/26394 has been described supra. The methods do not recite surgically removing the tumor or kits but these would have been obvious because the objective for tumor treatment is removal of the tumor and it would have been obvious once the tumor was located to surgically remove it as is common in the art. In addition, it would have been obvious to place the antibody and reagents in a kit for convenience as is done in the art.

Therefore, Claims 51, 53-54 lack an inventive step under PCT Article 33(3) as being obvious over WO 00/26394, 5/11/2000.

----- NEW CITATIONS -----

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

TIME LIMIT:

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.